11. The method of claim 10, further comprising the step of obtaining combinations of the peptides, derivatives, or fragments by chemical bonding.

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12. A method of using the peptide of claim 6 comprising orally administering the peptide to an individual to selectively promote growth of bifidobacteria, or selectively inhibit the growth of non-bifidobacteria, in the digestive tract.

REMARKS

Claims 6-12, presented hereby, replace claims 1, 4, and 5.

Claim 3 was withdrawn from consideration pursuant to restriction.

Claims 6-12 contain the subject matter of claims 1, 4, and 5 revised to address the rejection under 35 USC 112, ¶2, as explained below.

The specification is amended to correct two inadvertent, and apparent, clerical errors appearing the generic protein formulas appearing in the specification at page 3. Two of the generic formulas represent branched proteins, as indicated by the line connecting the polypeptide branch to the polypeptide backbone in each of protein formulas, i.e., connecting a carbon atom in the branch to the adjacent carbon atom in the backbone.

A new Abstract is submitted herewith, as a separate page, as required in the Office Action.

The objections to the specification set forth in the Office Action are poorly taken.

The three-letter code for amino acids is required only in the Sequence Listing. The single letter code for amino acids is appropriately used in the specification and claims. 378 CFR 1.821(a)(2).

The protein formulas appearing in the specification (at page 3) and claims, i.e., in present claim 7, are generic formulas covering proteins, which are not covered under the PTO Rules (i.e., Rules 821-825) governing biological sequence disclosures. This is because, inter alia, the Rules cover only sequences in which each amino acid is "specifically defined" (*cf.* 37 CFR 1.821(a)).

Reconsideration is requested with respect to the rejection under 35 USC 112, ¶1, for alleged lack of enablement.

Satisfaction of enablement under 35 U.S.C. 112, first paragraph,

> requires nothing more than objective enablement. . . . [A] specification . . . *must* be taken as complying with . . . 35 U.S.C. 112 *unless* there is reason to do doubt the objective truth of statements relied upon therein.

Staehelin v. Secher, 24 USPQ2d 1513, 1516 (BPA & I 1992) (*emphasis in original*). In order to sustain a rejection for lack of enablement under §112, first paragraph, the PTO must cite evidence in support of any allegations of non-enablement, in addition to explaining *why* it doubts the truth of statements of enablement made in the specification. *In re Sichert*, 196 USPQ 209 (CCPA 1977).

Lack of enablement is not demonstrated merely because the claim scope might, theoretically, cover embodiments that do not work; the function of the claims is not to specifically exclude possibly inoperative embodiments. *Atlas Powder v. E.I. du Pont de Nemours Co.*, 224 USPQ 409 (Fed. Cir. 1984). Even in an unpredictable area, such as chemistry, the PTO must advance reasons why a patent applicant's broad assertion of enablement is not true. *In re Bowen*, 181 USPQ 48 (CCPA 1974). In

order to sustain a rejection for lack of enablement under §112, and shift the burden to a patent applicant, the PTO must advance evidence or reasoning inconsistent with enablement. *Sichert, supra.* Lack of enablement under §112 is not established by mere allegations of undue breadth, that is, by merely arguing that claims read on non-disclosed embodiments. *Horton v. Stevens*, 7 USPQ2d 1245 (BPA & I 1988). In order to satisfy the requirements of §112, first paragraph, "it is not necessary to embrace in the claims or describe in the specification all possible forms in which the claimed principle may be reduced to practice." *Smith v. Snow*, 294 U.S. 1, 11 (1935). The law does not require an applicant to describe in his specification every conceivable embodiment of the invention. *SRI Int'l v. Matsushita Elec. Corp. of America*, 227 USPQ 577, 586 (Fed. Cir. 1985). Moreover, while working examples drawn to specific embodiments may be desirable, they are not *required* in order to satisfy enablement under §112. *In re Strahilevitz*, 212 USPQ 561 (CCPA 1982). It is well established that working examples are not necessary when one possessed of knowledge of ordinary skill in the art could practice the invention without the exercise of undue experimentation. *Ex parte Nardi*, 229 USPQ 79 (BPA & I 1986). "In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art." *Staehelin*, 24 USPQ2d at 1516.

In the present situation, the instant disclosure together with the knowledge possessed by one skilled provides more than enough information to practice the presently claimed invention without the exercise of undue experimentation. Accordingly, there is no lack of enablement, *Nardi, supra.*

Reconsideration is requested with respect to the rejection under 35 USC 112, ¶2, for alleged indefinite claims, in view of the changes in claim language effected by the instant amendment and the following remarks.

The correct test for indefinite claim language is whether one of ordinary skill in the art would be confused as to the meaning of subject matter defined by the language at issue. *In re Kroekel*, 183 USPQ 610 (CCPA 1974). Applying this test demonstrates that the language at issue satisfies the requirements of 35 USC 112, ¶2.

While *limitations* from the specification cannot be read into the claims, words in the specification are properly used during prosecution as an aid in *interpret existing claim limitations*. This distinction is examined in the decision *In re Donaldson Co. Inc.*, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994).

> The Commissioner confuses [1] impermissibly imputing limitations from the specification with [2] properly referring to the specification to determine the meaning of a particular word or phrase recited in a claim.

Claims are to be given their broadest reasonable interpretation during prosecution, but the definition of a claim limitation given by the Examiner cannot be different than would be given by one of ordinary skill in the art. *In re Cartright*, 49 USPQ2d 1464 (Fed. Cir. 1999). Moreover, the Examiner's definition of a claim limitation cannot conflict with the definition given in the specification. *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). The examiner must use the specification definition in construing the claims for comparison with the prior art.

> When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve

> a complete exploration of the applicant's invention and its relation to the prior art.

Zletz, 13 USPQ2d at 1322. Moreover, claim terms need not be "conventional" in the art, since a patent applicant is entitled to be his own lexicographer. *In re Castaing*, 166 USPQ 550 (CCPA 1970).

Applying the aforesaid standards to the present claims, taken together with the changes in claim language reflected by the present claims, with respect to the instances of allegedly indefinite claim language set forth in the statement of rejection, Applicants submit that the present claims satisfy the requirements of 35 USC 112, ¶2.

Reconsideration is requested with respect to the rejection under 35 USC 101 for including a recitation of use without process steps, in view of the instant Amendment.

In accordance with the instant amendment, the only claim containing a recitation of use is claim 12. Claim 12 recites the "method of using the peptide of claim 6 comprising orally administering the peptide to an individual to selectively promote growth of bifidobacteria, or selectively inhibit the growth of non-bifidobacteria, in the digestive tract." Since claim 12 recites the requisite process step, i.e., "orally administering the peptide to an individual," the rejection under §101 is overcome.

Atty. Docket No.: P65141US0
Serial No.: 09/508,095

Favorable action is requested.

Respectfully submitted,

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Marked up version of amendments to the specification

IN THE SPECIFICATION

At page 3, replace paragraph 2 with the following:

-- Preferably, peptides are used which have the following amino acid sequences [sequence (SEQ ID NO: 1-24, respectively in order of appearance)] :

R_1-EQLLRLKK-R_2, R_1-YLEQLLRLKKY-R_2, R_1-NRQRNILR-R_2,

R_1-YMNGMNRQRNILR-R, R_1-FQWQRNMRK-R_2, R_1-HTGLRRTA-R_2,

R_1-FTAIQNLRK-R_2, R_1-EVAARARVVW-R_2, R_1-WQRNMRKV-R_2,

R_1-LARTLKRLK-R_2, R_1-YKQKVEKV-R_2, R_1-LVRYTKKV-R_2,

R_1-KYLYEIARR-R_2, R_1-ARRARVVWCAVG-R_2, R_1-ARRARVVWCAVGE-R_2,

R_3-CIAL-R_4 R_3-CIAL-R_4

[R_1-ARRARVVWCAVG-R_2, R_1-ARRARVVWCAVGE-R_2,

R_3-CIAL-R_4 R_3-CIAL-R_4]

R_1-YQRRPAIAINNPYVPRTYYANPAVVRPHAQIPQRQYLPNSHPPTVVRRPNLHPSF-R_2,

R_1-GRRRRSVQWCIVSQPEATKFQWQRNMRRVRGPPVSCIKRDSPIQCIQA-R_2,

R_1-GRRRSVQWCAVSQPEATKCFQWQRNMRKVRGPPVSCIKRDSPIQCIQA-R_2,

R_1-GRRRRSVQWCAVSQPEATKCFQWQRNMRKVRGPPVSCIKRDSPIQCIQA-R,

R_1-VYQHQKAMPKPWIQPKTKVIPYVRYL-R_2, R_1-ARRARVVWAAVG-R_2,

R_1-CAVGGGCIAL-R_2,

R_1-RHTRKYWCRQGARGGCITL-R_2,

wherein

R_1, R_3 independently represents NH_2, an amino acid, or a peptide containing up to 100 amino acids, and

R_2, R_4 independently represents COOH, $CONH_2$, an amino acid, or a peptide containing up to 100 amino acids;

and the amided acetylated, sulfated, phosphorylated, glycosylated, oxidixed derivatives or fragments thereof having bifidogenic properties.

ABSTRACT

Peptides having bifidogenic properties are obtainable by the process of adding proteases to cow's milk or human milk, followed by incubation, centrifugation, acidification, purification by reverse phase HPLC and cation-exchange HPLC, culturing *Bifidobacterium bifidum* and *E. coli* in the presence of collected bifidogenic fractions, and isolation of the peptides having bifidogenic properties, and the isolated peptides can be amidated, acetylated, sulfated, phosphorylated, glycosylated, oxidized, or fragmented and still maintain their bifidogenic properties, and combination peptides having bifidogenic properties are obtainable by chemically bonding the peptides having bifidogenic properties, the amidated, acetylated, sulfated, phosphorylated, glycosylated, oxidized, or fragmented peptides having bifidogenic properties, or combinations thereof.

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